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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,016	03/12/2002	Heikki Hyoty	U 013757-2	2116

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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,016	HYOTY ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1,12-19,21 and 31-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11,20 and 22-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/4/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of group II in the reply filed on 3/22/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 12-19, 21, 31-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/22/2004.

Claim Objections

Applicant is advised that should claims 2-11 be found allowable, claims 20, 22-30 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

Claims 2-11, 20, 22-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use

the invention. All of these claims involve administering oral poliovirus to a patient in an amount effective to elicit a protective immune response against type I diabetes (IDDM). The specification provides epidemiological data consistent with the proposition that OPV reduces the incidence of type I diabetes, and that enterovirus infections are correlated to type I diabetes. The specification also teaches experiments where live polio vaccine was administered to transgenic mice followed by enterovirus infection, showing increased pathology but decreased viremia in response to the enterovirus infection. The specification suggests using an OPV dose corresponding to that which is used in the traditional Sabin-type OPV (specification page 9), and suggests repeated vaccinations.

On the other hand, a case-control study by Graves et al (Diabetes Care, 22:1694-1698, 1999) provides evidence that repeated doses of OPV do not prevent development of beta-cell autoimmunity in high-risk children. A very recent publication by the inventors and others (Viskari et al, Journal of Medical Virology 72:610-617, 2004) indicates that there is lingering disagreement in the art regarding the relationship between diabetes and enterovirus infection, e.g.: "...if enterovirus infections are a true risk factor for type 1 diabetes, as implied in several but not all reports..." (page 614, citations omitted).

The specification does not provide any definite teachings as to what amounts of OPV is required to effectively prevent IDDM, and does not provide any working examples demonstrating prevention of diabetes. Considering the low incidence of IDDM in the overall population, and the long interval between childhood immunization and the

development of IDDM, a large quantity of experimentation would be required to establish what dose, if any, is effective to prevent IDDM.

Considering the nature of the invention, the lack of agreement in the art (both prior to the invention and later) regarding the relationship between virus infection and IDDM, the quantity of experimentation required, the limited guidance and the absence of working examples, it is concluded that undue experimentation would be required to establish "an amount effective to elicit a protective immune response against Type I diabetes mellitus (IDDM)."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 6, 20, 22, are rejected under 35 U.S.C. 102(b) as being anticipated by Harjulehto-Mervaala et al (Clinical Infectious Diseases 18(3): 414-420, 1994, abstract only cited). The reference teaches administering OPV to pregnant women. Although the reference does not teach that vaccination prevents type I diabetes, this outcome would be an inherent result of the vaccination, if administration of OPV to a pregnant woman is indeed effective at preventing diabetes in the offspring.

Claims 2-4, 20, 23, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by the WHO Weekly Epidemiological Record (71:133-140, 1996). The reference teaches administering repeated doses of OPV to children starting at birth. Although the

reference does not teach that vaccination prevents type I diabetes, this outcome would be an inherent result of the vaccination, if repeated administration of OPV is indeed effective at preventing diabetes. Note that many countries routinely used 4 OPV administrations, and some used 7 administrations (e.g. Hong Kong, Mongolia).

The following claims appear to be free of the art. Claims 5, 25, the prior art does not appear to teach or suggest OPV booster vaccinations after completing the 1, 6, 10, 14-week infant vaccination schedule. Claims 6, 26, the prior art does not appear to teach or suggest OPV administration both pre-and post-natally. Claims 8-11, 27-30, the prior art does not teach or suggest combination of OPV with a vaccine against other enteroviruses.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/12/04

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800 1600